

Applicant's Responses to the Examiner's Rejections, Arguments and Objections**Faxing Papers into the Office**

Applicant/Owner will mail hard copies to the Office to facilitate communication.

Objections to the Disclosure

Applicant/Owner apologizes to the Examiner for not completely correcting the misspellings of messophilic. Correction is made in this Office Action Response and Amendment.

Rejection under 35 U.S.C. Sec. 112, 2nd Paragraph

Applicant/Owner has amended claim 15 to read:

15. The method for dewatering biological sludge according to claim 1, wherein:
said polymeric quaternary ammonium compound is added along with said cationic polyacrylamide.

Examiner's Position and Response to Owner/Applicant's Remarks

Examiner –

Owner has offered a lengthy response to the Examiner's Note set forth at page 3 of the 8/21/06 Office action. Owner's response suggests that Owner misunderstands the examiner's position. If true, perhaps owner's misunderstanding is due to the examiner's failure to adequately explain his position. The examiner attempts to clarify the examiner's position with the following additional remarks.

During prosecution of original application Serial No. 08/721,557, the examiner required an election of species. The embodiments referred to as "Method One" and "Method Two," which were covered by claims 1 – 16, were elected. Claims 17 – 32, which were directed to non-elected species "Method Three" and "Method Four" were cancelled. Claims 1 – 16 issued as US Pat. No. 5,846,435. This merged application / proceeding is both a reissue and reexamination of the '435 patent. Importantly, only

those claims directed to the Method One or Method Two embodiments of the original disclosure may be prosecuted in this merged reissue application / reexamination proceeding because the Method Three and Method Four embodiments were non-elected during prosecution of Application serial no. 08/721,557. Furthermore, if terminology or subject matter of the invention were described by applicant in the original disclosure only in connection with the non-elected species of Method Three and Method Four, then such terminology and subject matter should not be used in claims of the present merged application / proceeding because doing so would amount to claiming subject matter that was non-elected, withdrawn from consideration, and not examined during prosecution of the original application. Protecting through reissue or reexamination patent coverage for an invention that was not elected and withdrawn from consideration in the original application is not permitted.

In this particular case, the only embodiments of the invention that may be patented or confirmed in this merged reissue / reexamination proceeding are:

Method One: "the polyquaternary amine is added directly, along with a cationic polyacrylamide, to the biological sludge;" or

Method Two: "the polyquaternary amine and an anionic polyacrylamide are added separately [to the biological sludge]."

(Abstract, USP 5,846,435).

The examiner believes that the foregoing remarks should clarify the examiner's remarks made in the previous Office action (Office action, 8/21/06, at page 3) which are repeated, confirmed and maintained.

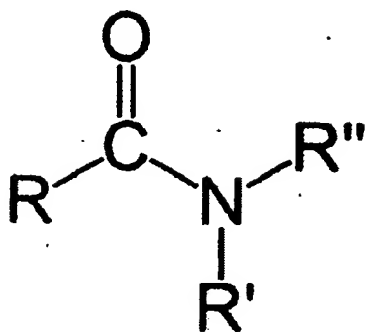
Applicant/Owner presents to the Examiner that a decision by the Examiner that "only" Method and Method Two can be patented or confirmed in this proceeding is improper according to MPEP 1412.01 and the case law referenced therein, e.g. *In re Doyle*, as discussed further by Applicant/Owner herein.

Examiner Note: "polymeric quaternary ammonium compound" and quaternary polyacrylamide

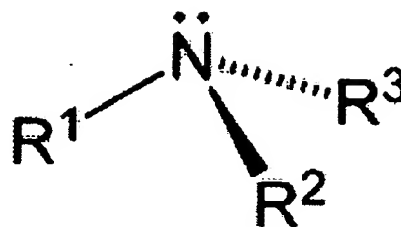
Examiner -

Whenever applicant / owner in the original disclosure used the term "polyquaternary amine,"¹ "polymeric quaternary ammonium compound," "polymeric quaternary amine," or the like in connection to his invention, he was referring to the polymers poly(diallyl dimethyl ammonium chloride) or poly(epichlorohydrin dimethyl amine), i.e., poly(DADMAC) or poly(epi-DMA). See, for example, col 1 lines 10-16; and Examples 1 – 3. These polymers were described in connection with only the Method One² or the Method Two³ embodiments of the invention. Never were any of these compounds added to the sludge in Method Three⁴ or Method Four⁵ embodiments. On the other hand, whenever applicant / owner in the original disclosure used the term "quaternized polyacrylamide," he was referring to a copolymer made from acrylamide and a quaternary ammonium compound, e.g., poly[acrylamide-co-DADMAC] or poly[acrylamide-co-(epi-DMA)] or poly[acrylamide-co-(allyl chloride)].⁶ See also Examples 4 – 7.

The upshot of this discussion is this: The **only** polymeric quaternary amine compounds that applicant taught that could be used in the Method One or Method Two inventions were poly(DADMAC) and poly(epi-DMA). In addition to these polymeric forms of quaternary amines, there was also the description and use of the non-polymeric quaternary amines of DADMAC and epi-DMA. Nowhere in the original disclosure did applicant describe the a polyacrylamide as a "polyquaternary amine" or the like at least for the reason that polyacrylamide, being an amide as shown at left below,



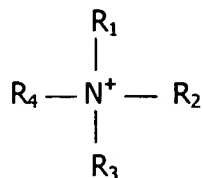
amide



amine

is not an amine at all, as shown at right above. Accordingly, the only embodiments amenable to patenting or confirming in this reissue / reexam are those in which DADMAC, epiDMA, polyDADMAC, or poly(epiDMA) is directly added to the biological sludge along with a cationic polyacrylamide (Method One) or in which DADMAC, epiDMA, polyDADMAC, or poly(epiDMA) and an anionic polyacrylamde are added separately to the biological sludge (Method Two).

Applicant/Owner wishes to agree with the Examiner that a polyacrylamide alone is not a polyquaternary amine, as referenced in Payne. Applicant/Owner would like to state that an anionic polyacrylamide cannot be a polyquaternary amine. Applicant/Owner would also like to state that "traditional polyacrylamides" used in the dewatering of mesophilic biological sludge, as taught by Applicant/Owner, Eberhard, McGrow, Payne and Dentel are cationic polyacrylamides, wherein the cationic moiety is obtained by reacting the acrylamide with a cationic monomer, as is known in the art. As taught by Applicant/Owner and Payne, these traditional cationic polyacrylamides used in the dewatering of messophilic biological sludge are not polymeric quaternary ammonium compounds. As the moiety of cationicity in a cationic polyacrylamide is be based upon nitrogen, as is known in the art, traditional cationic polyacrylamides used in the dewatering of messophilic biological sludge are secondary and tertiary amines; this is while the Examiner's drawing of an amine is that of a tertiary amine. In contrast to a tertiary amine, a quaternary amine (as defined by Applicant/Owner and referenced in dictionary definition previous) can be depicted by:



In relation to the teachings of the instant specification, Applicant/Owner would like to respectfully refer the Examiner to col. 3 lines 60 – 63 of the instant specification, wherein is stated:

“An additional object of the invention is to devise a method for dewatering of biological sludge that has been digested by a thermophilic digestion process with **polyquaternary amine** being used as the **primary component**.” **(Emphasis added)**

Applicant/Owner also wishes to respectfully refer the Examiner to col. 5 lines 2 – 9, which states:

“The significant improvements of this invention in sludge dewatering are accomplished by the addition of **polyquaternary amines** to the sludge. Di-allyl di-methyl ammonium chlorides (DADMAC) and epichlorohydrin di-methyl amine (epi-DMA) are two **preferred embodiments**.” **(Emphasis added)**

Further, Applicant/Owner wishes to respectfully refer the Examiner to col. 5 line 52 – col. 6 line 9, which states:

“Method one involves the addition of a **polyquaternary amine** directly to the sludge. Since the **polyquaternary amine does not contain enough molecular weight** for dewatering of the sludge, once the microflocs of sludge have formed from the **polyquaternary amine**, a **cationic polyacrylamide is added to form a floc that will dewater well**. The ratio of **polyquaternary amine** to cationic polyacrylamide appears to be near about 1:1 where the polyquaternary amine is of high molecular weight (e.g. from about 500,000 to about 3,000,000) and where the cationic polyacrylamide is of higher molecular weight (e.g. from about 5,000,000 to about 16,000,000). In a preferred embodiment, the ratio of the **polymeric quaternary ammonium compound** with respect to the cationic polyacrylamide is between about 1:10 to about 20:1. In a thermophilic digested sludge with a solids component of 4.4 percent, a total polymer dosage requirement of near 950 ppm is shown. **As the solids component of the sludge increases or decreases, the amount of polyquaternary amine and polyacrylamide increases or decreases proportionately**. The polymer concentration to solids component ratio (the ratio of

the total polymer dosage requirement to the percentage of solids component of the sludge) may vary from about 50 ppm:1 percent to about 300 ppm:1 percent, depending on the sludge type. **(Emphasis added)**

Further still, Applicant/owner refers the Examiner to col. 6 lines 9 – 44, which states:

“Method two involves the addition of a **polyquaternary amine** directly sludge. Since the **polyquaternary amine does not contain enough molecular weight dewatering** of the sludge, **an excess amount of the polyquaternary amine is added** so that a noticeable cationic overcharge exists within the microfloc system. This cationic overcharge will exist when the supernatant water is rather clear and the size of the microflocs ceases to grow with chemical addition. This requires approximately 20 to 30 percent addition increase of the **polyquaternary amine** as compared to method one. **An anionic polyacrylamide is then added for final floc formation.** The ratio of **polyquaternary amine** to **anionic polyacrylamide** appears to be near 10:1 where the polyquaternary amine is of high molecular weight (e.g. from about 500,000 to about 3,000,000) and where the anionic polyacrylamide is of higher molecular weight (e.g. from about 5,000,000 to about 15,000,000) and is 40 percent anionic. As in method one, in a preferred embodiment, the ratio of the **polymeric quaternary ammonium compound** with respect to the cationic polyacrylamide is between about 1:10 to about 20:1. In a thermophilic digested sludge with a solids component of 4.4 percent, a total polymer dosage requirement of near 950 ppm is shown. **As the solids component of the sludge increases or decreases, the amount of polyquaternary amine and polyacrylamide increases or decreases proportionately.** The polymer concentration to solids component ratio may vary from about 50 ppm:1 percent to about 300 ppm:1 percent, depending on the sludge type. CV 6140, as an emulsion copolymer of polyacrylamide with acrylic acid, is a preferable candidate for method two. CV 6140 has a 40% anionic charge density, a specific gravity of 1.03 at about 77 °F (25 °C), a freezing point of approximately 32 °F (0 °C), viscosity ranging from about 400 cps to 1200 cps at about 77 °F (25 °C), an activity rate of about 40% and a flash point of approximately 150 °F (65 °C).” **(Emphasis added)**

Further still yet, Applicant/owner refers the Examiner to col. 1 lines 13 – 25, which states:

“Examples of **polymeric quaternary ammonium compounds** are the di-allyl di-methyl ammonium chloride (DADMAC) variety and the epichlorohydrin di-methyl

amine (epi-DMA) variety. Further, cationic and anionic polyacrylamides, where the cationic or anionic moiety may result from various co-monomers in the polymerization process of polyacrylamide, have been applied in dewatering methods. **Traditional polyacrylamide polymers do not contain polyquaternization from allyl chloride or from epi-DMA.** Only within the last three years have polyacrylamides containing cationic monomers, based on allyl chlorides, been available. **(Emphasis Added)**

This is while Method 3 is described in col. 6 lines 44 – 58 as:

“Method three involves the addition of a **quaternized polyacrylamide** where the **cationic monomer of the polyacrylamide is derived from a polymeric quaternary ammonium compound.** **Allylic chloride and epichlorohydrin di-methyl amine** are preferred sources for the cationic monomer. **The most preferred embodiment of the quaternized polyacrylamide used is:**

a copolymer of polyacrylamide with a cationic monomer that is quaternized in the polyacrylamide, the copolymer having a specific gravity of 1.2 at about 77 °F (25 °C), a freezing point of approximately 23 °F (-5 °C), viscosity of less than 1200 cps at about 40 °F (4.4 °C), an activity rate of about 38% and a flash point of about 275 °F (135 °C.), (CV 5380).” **(Emphasis Added)**

This is while the instant specification as a lead in paragraph to the section “DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS” states in col. 4 Lines 33-39:

“The present invention is described in connection with one or more preferred embodiments. However, it should be understood that the invention is not limited to those embodiments. In contrast, the invention includes all alternatives, modifications and equivalents as may be included within the spirit and scope of the specification and of the appended claims.”

Therefore, the specification does not limit polyquaternary amines, polymeric quaternary ammonium compounds, to poly(DADMAC) and poly(epi-DMA) in any method. The specification refers to “polyquaternary amines”, e.g. genus, as the “significant improvements of this invention” while poly(DADMAC) and poly(epi-DMA) are referred to as “preferred embodiments”, e.g. preferred species. Further, there is no disclosure within Method One or Method Two to limit the quaternized moiety to a poly(DADMAC) or to poly(epi-DMA) or to DADMAC or to epi-DMA. This is while instead methods one and two each teach “polyquaternary amine”, e.g. polymeric quaternary ammonium

compound. Applicant/Owner would like to present to the Examiner that by the Examiner inserting such a limitation, e.g. poly(DADMAC) and poly(epi-DMA), that the Examiner is inserting limitations in the instant invention. In reference to Examples 1 – 4, an Example is an Example. Examples are to be illustrative of the instant invention and not to be limiting of the instant invention. This is while a polyquaternary amine is taught in Examples 6 and 7, wherein the polyquaternary amine is a quaternized polyacrylamide (ref. col. 6 lines 51 – 58).

In line with the above teachings from the instant specification, Applicant/Owner refers the Examiner to MPEP Section 2164.02, which states:

“For a claimed genus, **representative examples together with a statement applicable to the genus as a whole will ordinarily be sufficient if one skilled in the art** (in view of level of skill, state of the art and the information in the specification) would expect the claimed genus could be used in that manner without undue experimentation. Proof of enablement will be required for other members of the claimed genus only where adequate reasons are advanced by the examiner to establish that a person skilled in the art could not use the genus as a whole without undue experimentation.” (Emphasis added)

Applicant/Owner also presents to the Examiner that by claim differentiation the polymeric quaternary ammonium compound can not be limited to just poly(DADMAC) and poly(epi-DMA), e.g. claim 1 versus claims 2 and 3, as originally prosecuted in the instant invention. Also, claim 22 vs. 26, claim 33 vs. 36, 48 vs. 51, 55 vs. 58, and 67 vs. 68 demonstrate by claim differentiation that Applicant/Owner teaches a polymeric quaternary ammonium compound, e.g. genus, to be differentiated from poly(DADMAC) and poly(epi-DMA), e.g. “preferred species”.

Applicant/Owner then must conclude from the instant specification and asks that the Examiner to conclude from the instant invention specification that the instant invention specification does not limit the teaching of a polymeric quaternary ammonium compound to poly(DADMAC) and poly(epi-DMA).

Applicant/Owner would further like to respectfully present to the Examiner that the instant specification makes a genus teaching statement within the section labeled “DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT” **prior** to and **separate from** presentation of the four methods. Specifically, col. 5 lines 2 – 4 states:

“The significant improvements of this invention in sludge dewatering are accomplished by the addition of polyquaternary amines to the sludge. Di-allyl di-methyl ammonium chlorides (DADMAC) and epichlorohydrin di-methyl amine (epi-DMA) are two preferred embodiments. **(Emphasis added)**”

Further, as defined in dictionaries:

Hawley's Condensed Chemical Dictionary (Hawley's) defines an amine as:

amine: A class of organic compounds of nitrogen that may be considered as derived from ammonia (NH₃) by replacing one or more of the hydrogen atoms with alkyl groups. The amine is primary, secondary, or tertiary depending on whether one, two, or three of the hydrogen atoms are replaced. All amines are basic in nature, and usually combine readily with hydrochloric or other strong acids to form salt.

And, ammonium is defined in Webster's Ninth New Collegiate Dictionary (Webster's) as:

ammonium: an ion NH₄⁺ or radical NH₄ derived from ammonia by combination with a hydrogen ion or atom and known in compounds (as salts) that resemble in properties the compounds of the alkali metals and in organic compounds (as quaternary ammonium compounds)

And, quaternized nitrogen is defined in Hawley's as:

quaternary ammonium salt. A type of organic nitrogen compound in which the molecular structure includes a central nitrogen atom joined to four organic groups (the cation) and a negatively charged acid radical (the anion).”

And, poly is defined by Hawley's as:

poly-, A prefix signifying many. For example, a polymer is an aggregate formed by combination of a number of single molecules.

And, polymer is defined by Webster's as:

polymer: a chemical compound or mixture of compounds formed by polymerization and consisting essentially of repeating structural units

And, acrylamide is defined by Hawley's as:

acrylamide: CH₂CHCONH₂

And, polyacrylamide is defined by Hawley's as:

polyacrylamide: (CH₂CHCONH₂)_n

Therefore, a quaternized polyacrylamide is a specie under the genus of quaternized polyamines, e.g. polymeric quaternary ammonium compounds. This is while another specie would be poly(DADMAC) and another specie would be poly(epi-DMA); both, again, are under the genus polymeric quaternary ammonium compounds, e.g. quaternized polyamines. This is all while there are other specie of

polymeric quaternary ammonium compounds, as is known in the art; some of which have been presented to the Examiner previous in this proceeding.

In relation to the aforementioned teachings quoted from the instant specification and the further dictionary support, Applicant would like to respectfully refer the Examiner to MPEP 2164.08, which states:

Enablement Commensurate in Scope with the Claims [R-2]

All questions of enablement are evaluated against the claimed subject matter. The focus of the examination inquiry is whether everything within the scope of the claim is enabled. Accordingly, the first analytical step requires that the examiner determine exactly what subject matter is encompassed by the claims. See, e.g., *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244, 68 USPQ2d 1280, 1287 (Fed. Cir. 2003)(When a range is claimed, there must be reasonable enablement of the scope of the range. Here, the claims at issue encompassed amounts of silicon as high as 10% by weight, however the specification included statements clearly and strongly warning that a silicon content above 0.5% by weight in an aluminum coating causes coating problems. Such statements indicate that higher amounts will not work in the claimed invention.). The examiner should determine what each claim recites and what the subject matter is when the claim is considered as a whole, not when its parts are analyzed individually. No claim should be overlooked. With respect to dependent claims, 35 U.S.C. 112, fourth paragraph, should be followed. This paragraph states that "a claim in a dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers" and requires the dependent claim to further limit the subject matter claimed.

The Federal Circuit has repeatedly held that "the specification must teach those skilled in the art how to make and use the full scope of the claimed invention **without 'undue experimentation'**." *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). Nevertheless, not everything necessary to practice the invention need be disclosed. In fact, what is well-known is best omitted. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. **Further the scope of enablement must only bear a "reasonable correlation" to the scope of the claims.** See, e.g., *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

As concerns the breadth of a claim relevant to enablement, the only relevant concern should be whether the scope of enablement provided to one skilled in the art by the

disclosure is commensurate with the scope of protection sought by the claims. *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244, 68 USPQ2d 1280, 1287 (Fed. Cir. 2003); *In re Moore*, 439 F.2d 1232, 1236, 169 USPQ 236, 239 (CCPA 1971). See also *Plant Genetic Sys., N.V. v. DeKalb Genetics Corp.*, 315 F.3d 1335, 1339, 65 USPQ2d 1452, 1455 (Fed. Cir. 2003) (alleged "pioneer status" of invention irrelevant to enablement determination).

The determination of the propriety of a rejection based upon the scope of a claim relative to the scope of the enablement involves two stages of inquiry. The first is to determine how broad the claim is with respect to the disclosure. The entire claim must be considered. The second inquiry is to determine if one skilled in the art is enabled to make and use the entire scope of the claimed invention without undue experimentation.

How a teaching is set forth, by specific example or broad terminology, is not important. *In re Marzocchi*, 439 F.2d 220, 223-24 169 USPQ 367, 370 (CCPA 1971). A rejection of a claim under 35 U.S.C. 112 as broader than the enabling disclosure is a first paragraph enablement rejection and not a second paragraph definiteness rejection. Claims are not rejected as broader than the enabling disclosure under 35 U.S.C. 112 for noninclusion of limitations dealing with factors which must be presumed to be within the level of ordinary skill in the art; the claims need not recite such factors where one of ordinary skill in the art to whom the specification and claims are directed would consider them obvious. *In re Skrivan*, 427 F.2d 801, 806, 166 USPQ 85, 88 (CCPA 1970). One does not look to the claims but to the specification to find out how to practice the claimed invention. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1558, 220 USPQ 303, 316-17 (Fed. Cir. 1983); *In re Johnson*, 558 F.2d 1008, 1017, 194 USPQ 187, 195 (CCPA 1977). In *In re Goffe*, 542 F.2d 564, 567, 191 USPQ 429, 431 (CCPA 1976), the court stated:

[T]o provide effective incentives, claims must adequately protect inventors. To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for "preferred" materials in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts.

When analyzing the enabled scope of a claim, the teachings of the specification must not be ignored because claims are to be given their broadest reasonable interpretation that is consistent with the specification. "That claims are interpreted in light of the

specification does not mean that everything in the specification must be read into the claims." *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 957, 220 USPQ 592, 597 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 835 (1984).

The record must be clear so that the public will have notice as to the patentee's scope of protection when the patent issues. If a reasonable interpretation of the claim is broader than the description in the specification, it is necessary for the examiner to make sure the full scope of the claim is enabled. Limitations and examples in the specification do not generally limit what is covered by the claims.

The breadth of the claims was a factor considered in *Amgen v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir.), *cert. denied*, 502 U.S. 856 (1991). In the *Amgen* case, the patent claims were directed to a purified DNA sequence encoding polypeptides which are analogs of erythropoietin (EPO). The Court stated that:

Amgen has not enabled preparation of DNA sequences sufficient to support its all-encompassing claims. . . . [D]espite extensive statements in the specification concerning all the analogs of the EPO gene that can be made, there is little enabling disclosure of particular analogs and how to make them. Details for preparing only a few EPO analog genes are disclosed. . . . This disclosure might well justify a generic claim encompassing these and similar analogs, but it represents inadequate support for Amgen's desire to claim all EPO gene analogs. There may be many other genetic sequences that code for EPO-type products. Amgen has told how to make and use only a few of them and is therefore not entitled to claim all of them.

927 F.2d at 1213-14, 18 USPQ2d at 1027. **However, when claims are directed to any purified and isolated DNA sequence encoding a specifically named protein where the protein has a specifically identified sequence, a rejection of the claims as broader than the enabling disclosure is generally not appropriate because one skilled in the art could readily determine any one of the claimed embodiments.**

See also *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) (The evidence did not show that a skilled artisan would have been able to carry out the steps required to practice the full scope of claims which encompass "any and all live, non-pathogenic vaccines, and processes for making such vaccines, which elicit immunoprotective activity in any animal toward any RNA virus." (original emphasis)); *In re Goodman*, 11 F.3d

1046, 1052, 29 USPQ2d 2010, 2015 (Fed. Cir. 1993) (The specification did not enable the broad scope of the claims for producing mammalian peptides in plant cells because the specification contained only an example of producing gamma-interferon in a dicot species, and there was evidence that extensive experimentation would have been required for encoding mammalian peptide into a monocot plant at the time of filing); *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (Where applicant claimed a composition suitable for the treatment of arthritis having a potency of "at least" a particular value, the court held that the claim was not commensurate in scope with the enabling disclosure because the disclosure was not enabling for compositions having a slightly higher potency. Simply because applicant was the first to achieve a composition beyond a particular threshold potency did not justify or support a claim that would dominate every composition that exceeded that threshold value.); *In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991) (Given the relatively incomplete understanding in the biotechnological field involved, and the lack of a reasonable correlation between the narrow disclosure in the specification and the broad scope of protection sought in the claims, a rejection under 35 U.S.C. 112, first paragraph for lack of enablement was appropriate.).

If a rejection is made based on the view that the enablement is not commensurate in scope with the claim, the examiner should identify the subject matter that is considered to be enabled.

(Emphasis added)

This is all while there is evidence of copying and commercial success by others since Applicant/Owner's teachings; thereby, further demonstrating that the instant invention teaches polymeric quaternary ammonium compounds to those of ordinary skill in the art beyond that of poly(DADMAC) or a poly(epi-DMA). Applicant/Owner refers the Examiner to affidavits and declarations presented in this proceeding which evidence applications of the instant invention and which demonstrate use of a polyquaternary ammonium compound as a Mannich polymer and as a quaternized polyacrylamide in Los Angeles and in Texarkana, respectively.

Therefore, and in conclusion, by teachings obtained within the instant specification, clarification of the instant specification by dictionary definition, and copying/commercial success by others, as well as case law, it is obvious that the claim limitation "polymeric quaternary ammonium compound" is a genus; while in comparison, a quaternized polyacrylamide, poly(DADMAC), poly(Epi-DMA) or any other specific polymeric quaternary ammonium compound is a specie under the genus of polymeric

quaternary ammonium compounds. Put another way, under the genus of polymeric quaternary ammonium compounds are the species of poly(epi-DMA), poly(DADMAC), quaternized polyacrylamide, quaternized polyacrylamide comprising a DADMAC monomer and quaternized polyacrylamide comprising an Epi-DMA monomer as is taught in the instant invention and presented to the Examiner. This is while there is no teaching within the instant specification to "limit" the moiety of a polyquaternary amine, e.g. polymeric quaternary ammonium compound, as is being done by the Examiner. However, there is teaching within the instant specification in numerous locations, as referred herein by Applicant/Owner, to "preferred" polyquaternary amines, which are taught to be poly(DADMAC) and poly(epi-DMA).

35 U.S.C. Sec. 112 Rejections

Claims 33-37 and 40 – With all due respect to the Examiner, the Examiner is reading claim limitations into claims 33-37 and 40 which are not imposed by the instant specification. The instant specification does not limit the use of a polymeric quaternary ammonium compound with a polyacrylamide. Applicant/Owner refers the Examiner again to col. 3 lines 60 – 63 of the instant specification, wherein is stated:

“An additional object of the invention is to devise a method for dewatering of biological sludge that has been digested by a thermophilic digestion process with **polyquaternary amine** being used as the **primary component**.” **(Emphasis added)**

Applicant/Owner also wishes to respectfully refer the Examiner to col. 5 lines 2 – 9, which states:

“The significant improvements of this invention in sludge dewatering are accomplished by the addition of **polyquaternary amines** to the sludge. Di-allyl di-methyl ammonium chlorides (DADMAC) and epichlorohydrin di-methyl amine (epi-DMA) are two **preferred embodiments**.” **(Emphasis added)**

Further, Applicant/Owner wishes to respectfully refer the Examiner to col. 5 line 52 – col. 6 line 9, which states:

“Method one involves the addition of a **polyquaternary amine** directly to the sludge. Since the **polyquaternary amine does not contain enough molecular weight** for dewatering of the sludge, once the microflocs of sludge have formed from the **polyquaternary amine**, a cationic

polyacrylamide is added to form a floc that will dewater well. The ratio of polyquaternary amine to cationic polyacrylamide appears to be near about 1:1 where the polyquaternary amine is of high molecular weight (e.g. from about 500,000 to about 3,000,000) and where the cationic polyacrylamide is of higher molecular weight (e.g. from about 5,000,000 to about 16,000,000). In a preferred embodiment, the ratio of the polymeric quaternary ammonium compound with respect to the cationic polyacrylamide is between about 1:10 to about 20:1. In a thermophilic digested sludge with a solids component of 4.4 percent, a total polymer dosage requirement of near 950 ppm is shown. As the solids component of the sludge increases or decreases, the amount of polyquaternary amine and polyacrylamide increases or decreases proportionately. The polymer concentration to solids component ratio (the ratio of the total polymer dosage requirement to the percentage of solids component of the sludge) may vary from about 50 ppm:1 percent to about 300 ppm:1 percent, depending on the sludge type. **(Emphasis added)**

Further still, Applicant/owner refers the Examiner to col. 6 lines 9 – 44, which states:

“Method two involves the addition of a polyquaternary amine directly sludge. Since the polyquaternary amine does not contain enough molecular weight dewatering of the sludge, an excess amount of the polyquaternary amine is added so that a noticeable cationic overcharge exists within the microfloc system. This cationic overcharge will exist when the supernatant water is rather clear and the size of the microflocs ceases to grow with chemical addition. This requires approximately 20 to 30 percent addition increase of the polyquaternary amine as compared to method one. An anionic polyacrylamide is then added for final floc formation. The ratio of polyquaternary amine to anionic polyacrylamide appears to be near 10:1 where the polyquaternary amine is of high molecular weight (e.g. from about 500,000 to about 3,000,000) and where the anionic polyacrylamide is of higher molecular weight (e.g. from about 5,000,000 to about 15,000,000) and is 40 percent anionic. As in method one, in a preferred embodiment, the ratio of the polymeric quaternary ammonium compound with respect to the cationic polyacrylamide is between about 1:10 to about 20:1. In a thermophilic digested sludge with a solids component of 4.4 percent, a total polymer dosage requirement of near 950 ppm is shown. As the solids component of the sludge increases or decreases, the amount of polyquaternary amine and polyacrylamide increases or decreases proportionately. The polymer concentration to solids component ratio may vary from about 50 ppm:1 percent to about 300 ppm:1 percent,

depending on the sludge type. CV 6140, as an emulsion copolymer of polyacrylamide with acrylic acid, is a preferable candidate for method two. CV 6140 has a 40% anionic charge density, a specific gravity of 1.03 at about 77 °F (25 °C), a freezing point of approximately 32 °F (0 °C), viscosity ranging from about 400 cps to 1200 cps at about 77 °F (25 °C), an activity rate of about 40% and a flash point of approximately 150 °F (65 °C).” **(Emphasis added)**

Therefore, it is only Methods One and Two which teach the need of a polyacrylamide, cationic and anionic, respectively, along with the primary component. Applicant/Owner refers the Examiner to the teachings within Methods One and Two, wherein it is the molecular weight of the polyquaternary amine, e.g. polymeric quaternary ammonium compound, which requires a polyacrylamide. Specifically, each of methods one and two teach “[s]ince the polyquaternary amine does not contain enough molecular weight dewatering”. Therefore, by requiring a claim limitation of polyacrylamide, the Examiner is either inserting a limitation into the instant teachings outside of Methods 1, 2, 3 and 4; or, the Examiner is limiting claim scope specifically to Methods 1 and 2.

Applicant/Owner refers the Examiner to previous argument on pages 17 – 25 of this Office Action Response. Further, please refer to MPEP 1412.01 as well as *In re Doyle*, 293 F.3d 1355, 63 USPQ2d 1161 (Fed. Cir. 2002), which is attached herein for the Examiner’s convenience. Applicant/Owner presents to the Examiner that claim 33, as well as claims 55 and 67, are “linking claim[s]” as is presented *In re Doyle*. As linking claims, claim 33, as well as claims 55 and 67, are not a part of the previous Examiner’s restriction requirement; as, neither claim 33, 55 nor 67 is taught in methods 1, 2, 3 or 4. Therefore, as in *In re Doyle*, claims 33, 55 and 67 are separate from the restriction requirement and allowance of claims 33, 55 and 67 as written does not affect the previous agreed to restriction requirement or the deal made there from. This is all while claims 33, 55 and 67 have obtained commercial success by others since Applicant/Owner’s teachings; thereby, further demonstrating that the instant invention teaches polymeric quaternary ammonium compounds to those of ordinary skill in the art beyond Methods 1 and 2. Applicant/Owner refers the Examiner to affidavits and declarations presented in this proceeding which evidence applications of the instant invention and which demonstrate use of a polyquaternary ammonium compound as a Mannich polymer and as a quaternized polyacrylamide in Los Angeles and in Texarkana, respectively).

Claims 8, 10-13 – Applicant/Owner has removed from claim 8 the claim limitation “cationic overcharge” and limited claim 8 to “said polyacrylamide is anionic”. This is while claim 1,

the claim from which claim 8 depends, has been limited to "adding a cationic or separately adding an anionic polyacrylamide to the biological sludge".

Applicant/Owner repeated this type of amendment to claims 38 and 71, which now state:

38. The method of claim 35, further comprising the addition of an anionic polyacrylamide for final floc formation.

71. The sludge composition of claim 67, further comprising a cationic or an anionic polyacrylamide.

Claim 24 – Claim 24 has been amended to state:

24. The method of claim 22, wherein said polymeric quaternary ammonium compound comprises a molecular weight in the range of about 500,000 to about 3,000,000 and said cationic polyacrylamide comprises a molecular weight in the range of about 5,000,000 to about 16,000,000.

Claims 47 and 54 – Applicant/Owner has amended claims 47 and 54 in a manner consistent with the claim amendments to claim 24. Specifically:

47. The sludge composition of claim 41, wherein said polymeric quaternary ammonium compound comprises a molecular weight in the range of about 500,000 to about 3,000,000; wherein

said polyacrylamide comprising a cationic moiety comprises a molecular weight in the range of about 5,000,000 to about 16,000,000; or wherein

said polyacrylamide comprising an anionic moiety comprises a molecular weight in the range of about 5,000,000 to about 15,000,000.

54. The sludge composition of claim 48, wherein said polymeric quaternary ammonium compound comprises a molecular weight in the range of about 500,000 to about 3,000,000, wherein

said polyacrylamide comprising a cationic moiety comprises a molecular weight in the range of about 5,000,000 to about 16,000,000; or wherein

said polyacrylamide comprising an anionic moiety comprises a molecular weight in the range of about 5,000,000 to about 15,000,000.

Claims 34 and 71 – While the instant specification teaches the importance of molecular weight in numerous locations, teaches the importance of molecular weight in Methods One and Two, and teaches in relation to polyquaternary amines in col. 5 lines 31-32, “The higher molecular weight polyquaternary amines demonstrate improved performance”, Applicant/Owner agrees that there is no specific teaching in the instant specification that the polyquaternary amine, polymeric quaternary ammonium compound, comprises a molecular weight of “specifically” of greater than 5,000,000. Therefore, Applicant/Owner has canceled claims 34 and 71. Applicant/Owner, however, would like to place in the prosecution file and requests the Examiner note that the teachings in the instant invention and in the instant claims direct one of ordinary skill in the art to higher molecular weight polymers for final floc formation, wherein many instances said higher molecular weight polymers comprise a molecular weight of greater than about 5,000,000.

Claims 24, 47 and 54 – Applicant/owner has amended claim 24 to state “about 16,000,000”. Further, Applicant/Owner has amended claims 47 and 54 to state “wherein said polyacrylamide comprising a cationic moiety comprises a molecular weight in the range of about 5,000,000 to about 16,000,000; or wherein said polyacrylamide comprising an anionic moiety comprises a molecular weight in the range of about 5,000,000 to about 15,000,000”.

35 U.S.C. 103(a) Rejections

Eberhard (in view of Williams) and McGrow (in view of Reimschuessel and USP 5178774 to Payne) for Claims 1 – 2, 4 – 8, 10 – 13, 15 – 16, 19, 22, 24 – 28, 33 – 38, 40, 41, 44 – 48, 51 – 55, 58 – 61, 67 – 71, 73, 75 – Applicant/Owner can find no argument in reference to this rejection within this Office Action; therefore, Applicant/Owner will work from the Examiner’s previous Arguments and combine with the following argument.

Eberhard (in view of Williams) and McGrow (in view of Reimschuessel and USP 5178774 to Payne) for Claims 1 – 2, 4 – 8, 10 – 13, 15 – 16, 19, 22, 24 – 28, 33 – 38, 40 – 41, 44 – 48, 51 – 55, 58, 67 – 71, 73

Applicant/Owner wishes to point out an area of agreement between the Examiner and Applicant/Owner; that is, while Eberhard does teach the dewatering of thermophilic bio-solids, Eberhard does not teach the use of a polyquaternary amine, e.g. polymeric quaternary

ammonium compound, as primary component in the dewatering of bio-solids from a thermophilic digestion process.

In relation to Williams, as the Examiner presents no argument of rebuttal to Applicant/Owner, Applicant/Owner concludes that the previous argument of Applicant/Owner in relation to Williams is valid with the Examiner. Said argument by Applicant/Owner is that Williams does not teach or suggest to dewater a biological sludge, much less a biological sludge from a thermophilic digestion process. Nor does Williams comprise a teaching or suggestion as to the use of a polyquaternary amine.

Therefore, there is no teaching or suggestion in Eberhard or in Williams to dewater a biological sludge from a thermophilic digestion process, wherein a polyquaternary amine is the primary component.

In relation to McGrow, while Applicant/Owner previously traversed the McGrow Citation twice, Applicant/Owner would like to respectfully present to the Examiner that both the industry and the assignee of McGrow, e.g. Allied Colloids, the 3rd Party Requestor of this proceeding, were unable to develop the instant invention after years of attempt prior to the teaching of Applicant/Owner.

Applicant/Owner would like to respectfully present to the Examiner that during Applicant/Owner's Teachings at College Station, as identified in Applicant/Owner's Declaration and in the Examples of the instant invention, College Station did not practice the teachings of the instant invention or that of the instant claims.

Further, if McGrow were obvious in the instant invention then why would not McGrow or the assignee of McGrow, e.g. Allied Colloids, have practiced the teachings of McGrow in the instant invention prior to Applicant/Owner's Teachings or at least prior to Applicant/Owner's teachings at College Station, Texas? As identified in the previous declaration of Richard A. Haase and of Audrey L. Haase, it was only after Applicant/Owner's teachings of the instant invention and of the instant claims at College Station that Allied Colloids, 3rd Party Requestor, was able to practice the instant invention. In short, the assignee of McGrow had to copy the instant invention and the instant claims from Applicant/Owner after the teachings of Applicant/Owner in order to realize the instant invention. If the instant invention was non-obvious to the inventor of McGrow and/or the assignee of McGrow, then the instant invention and the instant claims must be non-obvious. Again, as stated previously to the Examiner, McGrow does not teach the dewatering of biological sludge from a thermophilic digestion process. In contrast, McGrow teaches improvements in relation to coring and to under dosing

in the dewatering of mesophilic biological sludge; therein, is teaching difference between McGrow and the instant invention, as well as the instant claims. At College Station and at all locations visited by Applicant, "traditional polyacrylamide polymers used for dewatering [e.g. cationic polyacrylamides alone as identified in McGrow, Dentel and the instant specification] have been shown to perform very poorly in tests for dewatering of sludge from a thermophilic digestion process" (ref. instant specification col. 1 lines 33 – 33).

The above argument is furthered by MPEP 2141.02, which states:

"[A] patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified. This is part of the 'subject matter as a whole' which should always be considered in determining the obviousness of an invention under 35 U.S.C. § 103." *In re Spinnoble*, 405 F.2d 578, 585, 160 USPQ 237, 243 (CCPA 1969). However, "discovery of the cause of a problem ... does not always result in a patentable invention. . . . **[A] different situation exists where the solution is obvious from prior art which contains the same solution for a similar problem.**" *In re Wiseman*, 596 F.2d 1019, 1022, 201 USPQ 658, 661 (CCPA 1979) (emphasis in original)." **(Emphasis added)**

As previously presented to the Examiner by Applicant/Owner, McGrow does not teach either the dewatering of biological sludge from a thermophilic digestion process or the use of a polymeric quaternary ammonium compound to overcome the repulsive forces present in a biological sludge from a thermophilic digestion process, e.g. the source of the problem. McGrow teaches the sequential use of a coagulant and a flocculant to eliminate coring and reduce underdosing. Specifically, McGrow in col. 6 lines 30 – 45 states:

"Compared to the traditional methods using the high molecular weight flocculant alone, the method of the invention gives numerous advantages. The flocs are small, evenly structured and highly filterable and have good shear stability, and the system is relatively resistant to overdosing. Thus **the risk of the formation of gelatinous flocs with the consequential disadvantages of coring** and reduced productivity can be avoided. In particular, higher cake dry solids can be obtained, again because of the better floc structure. The process is also less susceptible to **underdosing**, which previously would have led to poor filterability and longer cycle times. Thus, overall, the process can give reduced cycle time, drier cake, better utilization of the capacity of the filter or belt press, improved filtrate quality, better cake release from the cloth, and cleaner filter cloths." **(Emphasis added)**

The above is in strong contrast to the challenges associated with the dewatering of a biological sludge from a thermophilic digestion process, as taught by Applicant/Owner. As demonstrated by Applicant/Owner on belt filter presses and on centrifuges, biological sludge from a thermophilic digestion process does not have a challenge relating to coring or underdosing. Quite the contrary, the sludge from a thermophilic digestion process has demonstrated challenges to form a floc; therefore, coring and underdosing are not issues in the dewatering of biological sludge from a thermophilic digestion process. Further, the biological sludge from a thermophilic digestion process has demonstrated challenges associated with overdosing. As taught by Applicant/Owner in the instant invention specification col. 1 lines 30 – 34:

“Meanwhile, traditional polyacrylamide polymers used for dewatering have been shown to **perform very poorly in tests for dewatering of sludge that has been digested by any thermophilic digestion process.**” (Emphasis added)

Applicant/Owner also teaches in col. 2 lines 25 – 36:

“Despite the disadvantages of mesophilic bacteria, **mesophilic bacteria are preferable in relation to the dewatering of digested sludge. Mesophilic bacteria naturally secrete a polysaccharide which acts as a tackifier providing a chemical mechanism of floc formation. This chemical mechanism is an aid to traditional cationic polyacrylamides to begin the dewatering process. However, thermophilic bacteria do not secrete a tackifying polysaccharide. Furthermore, thermophilic bacteria naturally repel each other.** This repelling nature of thermophilic bacteria makes the dewatering of sludge from the thermophilic digestion process expensive and difficult.” (Emphasis added)

Applicant/Owner also teaches and demonstrates in col. 4 lines 59 – 65:

“The best performing traditional polyacrylamide technology utilized at the site of this invention was Nalco 9909, manufactured by Nalco Chemical, Inc. Usage of Nalco 9909 results in a **dry polymer dosage often near 2,000 ppm and usually near 1,700 ppm treating sludge near 4 percent solids. Even at this dosage, plant throughput was at 20 percent of rated capacity.**” (Emphasis added)

This horrendous chemical dosage is in very strong contrast to any discussion of underdosing, as taught by McGrow.

In direct support of the facts of copying by others, e.g. assignee of McGrow, as evidenced in the declarations submitted, Applicant/Owner would like to cite MPEP 716.06, which states:

“Evidence of copying was persuasive of nonobviousness when an alleged infringer tried for a substantial length of time to design a product or process similar to the claimed invention, but failed and then copied the claimed invention instead. *Dow Chem. Co. v. American Cyanamid Co.*, 837 F.2d 469, 2 USPQ2d 1350 (Fed. Cir. 1987).” (Emphasis added)

To further emphasize the length of time to copy, McGrow was originally filed on October 4, 1990. This is while the previously presented US EPA Document TBS Prakasam, et al. *Effect of Recycling Thermophilic Sludge on the Activated Sludge Process*, EPA Project Summary 5, Sept. 1990 states under the heading of Dewaterability:

“Capillary suction time (CST) measurements at various polymer dosages indicated that mesophilic sludge required a lower polymer dosage than did the thermophilic sludge (10 vs. 22.5 kg/dry tonne) to achieve the minimum CST that was possible. The thermophilic sludge, however, exhibited highest floc strength than did the mesophilic sludge.

Pilot scale centrifuge studies confirmed that the thermophilic sludge required a higher polymer dosage than did the mesophilic sludge. At optimal polymer dosages, those studies also indicated that the mesophilic sludge approached 100% solids capture whereas the thermophilic solids approached a maximum of 96% solids capture. The lower solids capture with thermophilic sludge probably resulted from the higher concentration of fine particles in it than in the mesophilic sludge.”

The report goes on to recommend that:

“Based on the lack of effect on sludge mass and the increase in digestion capability required, the Torpsy process is not recommended for Chicago’s conventional rate activated sludge plants. Nor is thermophilic digestion as the terminal sludge digestion process recommended if the sludge is to be used at a site with nearby neighbors.”

Therefore, as the instant invention was copied by the assignee of McGrow only after teaching by Applicant/Owner, it is obvious that the teachings of the instant invention were not obvious to the assignee of McGrow from the 1990 teachings of McGrow until the teachings of the Applicant/Owner in 1996. Further, McGrow published in 1993. At a time wherein McGrow was available to the

industry, from 1993 to the time of the instant invention (1996), if the teachings of McGrow had made the instant invention obvious, then during that time of three years, the instant invention would have been taught and practiced. This is all while the difficulty to dewater biological sludge from a thermophilic digestion process was well known as far back as 1990, as evidenced by the US EPA. Therefore, one must conclude that McGrow could not make the instant invention or the instant claims obvious to the assignee of McGrow over a time of 6 years. And, if the industry could not make the instant invention and the instant claims obvious over a time of 3 years while having McGrow available, then McGrow must not make the instant invention and the instant claims obvious to the industry. If the instant claims had been obvious in 1996, then College Station would have been operating with the instant invention during the visit of Applicant/Owner or prior to the teachings of Applicant/Owner to College Station and to Allied Colloids, 3rd Party Requestor.

The same argument is presented for Texarkana, Texas, as evidenced in the aforementioned and presented affidavits and declarations. In the case of Texarkana, Applicant/Owner taught the instant invention and the instant claims to the wastewater operations of Texarkana from 1996 to 1998. The instant invention and instant claims were copied in Texarkana at the Texarkana Wastewater Facility in 1998. Therefore, in the case of Texarkana, it took the industry 5 years and the assignee of McGrow 8 years to copy the instant invention.

In conclusion, the instant invention is non-obvious by the teachings of McGrow, as is evidenced in the industry and by the assignee of McGrow, 3rd Party Requestor.

The Examiner quotes from McGrow that in 1990 "it was 'standard practice' to facilitate the dewatering of an aqueous suspension by adding coagulant and/or flocculant to it." This is while Dentel, e.g. Steven K. Dentel, *Evaluation of Dual Chemical Conditioning and Dewatering of Aerobically Digested Biosolids*, August 18, 1996, teaches away from the use of a coagulant and a flocculant in combination to dewater biological sludge. Specifically, Dentel states on page 11-29:

"The use of ferric chloride or HDTMA (a quaternary salt) as a preconditioner can reduce the polymer requirement, but this is not a cost effective option at current prices for these additives."

This is while a second article by Dentel, *Evaluation of Dual Chemical Conditioning and Dewatering of Anaerobically Digested Biosolids*, June 1995, and previously cited in this proceeding concludes on page 9 that:

"As a rule of thumb, it appears that adding a proportion of one chemical's optimum dosage reduces the requirement for the other by the same amount. ..If this rule were invariably true, it

would always be most economical to use only one of the conditioning chemicals by itself. However, the CST results also indicated that sole use of ferric chloride or HDTMA (quaternary salt) did not provide adequate dewaterability even at the optimum dose. . .”

And, on page 11 that:

“The use of ferric chloride or HDTMA (a quaternary salt) as a preconditioner can reduce the polymer requirement, this is not a cost effective option at current prices for these additives.”

Therefore, at late as 1996 it was not known to be economical to “precondition” a biological sludge with a polyquaternary amine, regardless of the teachings of McGrow. If McGrow made it obvious to precondition a sludge, bio-solids, with a polyquaternary ammine, then why did Dentel, working for a well established University, directly teach away from the teachings of McGrow 6 years later?

Further, the Dentel article is more timely to the instant invention than is McGrow. The Dentel article published in 1995 and again in 1996, wherein the Fall of 1996 is the time frame of the instant invention. Therefore, Dentel is a much closer reference to the instant invention and the instant claims than is McGrow. Applicant/Owner refers the Examiner to MPEP 716.02(e):

Applicants may compare the claimed invention with prior art that is more closely related to the invention than the prior art relied upon by the examiner. *In re Holladay*, 584 F.2d 384, 199 USPQ 516 (CCPA 1978); *Ex parte Humber*, 217 USPQ 265 (Bd. App. 1961) (Claims to a 13-chloro substituted compound were rejected as obvious over nonchlorinated analogs of the claimed compound. Evidence showing unexpected results for the claimed compound as compared with the 9-, 12-, and 14- chloro derivatives of the compound rebutted the *prima facie* case of obviousness because the compounds compared against were closer to the claimed invention than the prior art relied upon.).

In conclusion, it is obvious from University work, the industry and from the assignee of McGrow that McGrow did not make the instant invention or the instant claims obvious. Applicant/Owner refers the Examiner to MPEP 2145 D, which states:

References Teach Away from the Invention or Render Prior Art Unsatisfactory for Intended Purpose

In addition to the material below, see MPEP § 2141.02 (prior art must be considered in its entirety, including disclosures that teach away from the claims) and MPEP § 2143.01

(proposed modification cannot render the prior art unsatisfactory for its intended purpose or change the principle of operation of a reference).

1. The Nature of the Teaching Is Highly Relevant

A prior art reference that "teaches away" from the claimed invention is a significant factor to be considered in determining obviousness; however, "the nature of the teaching is highly relevant and must be weighed in substance. A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994) (Claims were directed to an epoxy resin based printed circuit material. A prior art reference disclosed a polyester-imide resin based printed circuit material, and taught that although epoxy resin based materials have acceptable stability and some degree of flexibility, they are inferior to polyester-imide resin based materials. The court held the claims would have been obvious over the prior art because the reference taught epoxy resin based material was useful for applicant's purpose, applicant did not distinguish the claimed epoxy from the prior art epoxy, and applicant asserted no discovery beyond what was known to the art.).

Furthermore, "the prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed...." *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004). **(Emphasis added)**

2. References Cannot Be Combined Where Reference Teaches Away from Their Combination

It is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983) (The claimed catalyst which contained both iron and an alkali metal was not suggested by the combination of a reference which taught the interchangeability of antimony and alkali metal with the same beneficial result, combined with a reference expressly excluding antimony from, and adding iron to, a catalyst.).

Along with MPEP 2141.02 VI, which states:

PRIOR ART MUST BE CONSIDERED IN ITS ENTIRETY, INCLUDING DISCLOSURES THAT TEACH AWAY FROM THE CLAIMS

A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984) (Claims were directed to a process of producing a porous article by expanding shaped, unsintered, highly crystalline poly(tetrafluoroethylene) (PTFE) by stretching said PTFE at a 10% per second rate to more than five times the original length. The prior art teachings with regard to unsintered PTFE indicated the material does not respond to conventional plastics processing, and the material should be stretched slowly. A reference teaching rapid stretching of conventional plastic polypropylene with reduced crystallinity combined with a reference teaching stretching unsintered PTFE would not suggest rapid stretching of highly crystalline PTFE, in light of the disclosures in the art that teach away from the invention, i.e., that the conventional polypropylene should have reduced crystallinity before stretching, and that PTFE should be stretched slowly.).

However, "the prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed...." *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004). See also **MPEP § 2123**.

In relation to Reimschuessel, as the Examiner presents no argument of rebuttal to Applicant/Owner, Applicant/Owner concludes that the previous argument of Applicant/Owner in relation to Reimschuessel is valid with the Examiner. Said argument by Applicant/Owner is that, Reimschuessel is totally lacking in any teaching as to a polymeric quaternary ammonium compound in dewatering biological sludge from a thermophilic digestion process. Therefore, there is no teaching within Reimschuessel to use the Percol DADMAC stated therein in the dewatering of biological sludge from a thermophilic digestion process.

In relation to Payne, as the Examiner presents no argument of rebuttal to Applicant/Owner, Applicant/Owner concludes that the previous argument of Applicant/Owner in relation to Payne is valid with the Examiner. Said argument by Applicant/Owner is that, Payne has no teaching as to the dewatering of any biological sludge from a thermophilic digestion process. Payne does describe ways to manufacture a polyacrylamide comprising a quaternized moiety; however, Payne does not teach or suggest the importance of a quaternized moiety, e.g. polymeric quaternary ammonium compound, in the dewatering of biological sludge from a thermophilic digestion process.

If all of the above technical and legal arguments are not enough, then there is the teaching of the US EPA, as previously presented in this proceeding. Specifically, the US EPA document TBS Prakasam, et al. *Effect of Recycling Thermophilic Sludge on the Activated Sludge Process*, EPA Project Summary 5, Sept. 1990 states under the heading of Dewaterability:

“Capillary suction time (CST) measurements at various polymer dosages indicated that mesophilic sludge required a lower polymer dosage than did the thermophilic sludge (10 vs. 22.5 kg/dry tonne) to achieve the minimum CST that was possible. The thermophilic sludge, however, exhibited highest floc strength than did the mesophilic sludge.

Pilot scale centrifuge studies confirmed that the thermophilic sludge required a higher polymer dosage than did the mesophilic sludge. At optimal polymer dosages, those studies also indicated that the mesophilic sludge approached 100% solids capture whereas the thermophilic solids approached a maximum of 96% solids capture. The lower solids capture with thermophilic sludge probably resulted from the higher concentration of fine particles in it than in the mesophilic sludge.”

The report goes on to recommend that:

“Based on the lack of effect on sludge mass and the increase in digestion capability required, the Torpsy process is not recommended for Chicago’s conventional rate activated sludge plants. Nor is thermophilic digestion as the terminal sludge digestion process recommended if the sludge is to be used at a site with nearby neighbors.”

Therefore, at a time wherein all of the Examiner’s citations were available, the US EPA, a pre-eminent authority, was not able to practice the instant invention from the available teachings, e.g. the Examiner’s citations. Therefore, it was not obvious in 1990, regardless of the statements by McGrow regarding previous industry use, to condition biological sludge from a thermophilic digestion process with a polymeric quaternary ammonium compound.

This is while at the time of the instant invention, those of ordinary skill in the art would have had available all of the above references. Therefore, for one of ordinary skill in the art to have developed the instant invention and the instant claims at the time of the instant invention, one of ordinary skill in the art would have had to: 1) apply McGrow to the dewatering of thermophilic bio-solids, when there is no teaching in McGrow in relation to thermophilic bio-solids, 2) ignore the fact that cationic polyacrylamides alone are unsuccessful in the watering of

thermophilic bio-solids, as described in the instant invention, and use a cationic polyacrylamide anyway, 3) ignore the teachings in McGrow which refer to coring and underdosing, neither of which is the challenge with the dewatering of thermophilic bio-solids, 4) ignore the teachings of Dentel and apply a polyquaternary amine as a conditioner to sludge from a thermophilic digestion process, 5) apply all of the above in light of Eberhard, while Eberhard teaches the use of an enzyme and a chelant, all the while ignoring the use of an enzyme and a chelant as taught in Eberhard, while 6) replacing both the enzyme and the chelant in Eberhard with a polymeric quaternary ammonium compound (again wherein Dentel teaches away from such use and is a closer reference than McGrow).

Applicant/Owner would like to present to the Examiner that such an irrational path is not a path for one of ordinary skill in the art, or quite frankly, for one of expert skill in the art; there are just too many irrational decisions which must be made with the cited references at the time of the instant invention without having the teaching and/or understanding of the source of the problem as taught in the instant invention. Most importantly, obviousness to try applies to teachings for the same purpose. At the time of the instant invention there was no obviousness to try conditioning of ANY biological sludge with a polyquaternary amine prior to the use of a cationic polyacrylamide due to the teachings of Dentel. This is while due to the teachings of McGrow, the only reason to go against Dentel would be in the instances of **"coring" or of "underdosing", neither of which is remotely an issue with the dewatering of thermophilic bio-solids.** This is while the **instant invention is for a different purpose, e.g. the dewatering of "thermophilic" bio-solids; and, it would have been obvious to one of ordinary skill in the art that the dewatering of thermophilic bio-solids is a "different purpose" than the dewatering of mesophilic bio-solids, as mesophilic bio-solids are traditionally dewatered with a cationic polyacrylamide, while as taught and demonstrated in the instant invention, thermophilic bio-solids are difficult at best to dewater with a cationic polyacrylamide. Therefore, and without question, to one of ordinary skill in the art, the dewatering of mesophilic bio-solids and the dewatering of thermophilic bio-solids are different purposes. This is while McGrow, Dentel, Wilson and Payne are different purposes than the instant invention, e.g. mesophilic bio-solids while the instant invention is thermophilic bio-solids.** Then, in order to develop the instant invention, one of ordinary skill in the art would have to take the teachings of McGrow for dewatering challenges in relation to mesophiles, which are not at all an issue with thermophiles, and apply McGrow to thermophiles, again different purposes, while ignoring the teachings in Eberhard as to the

use of a chelant and dispersant while replacing the chelant and the dispersant in Eberhard with a polymeric quaternary ammonium compound, which again goes against a very timely reference in Dentel, all the while ignoring the enzyme and chelant teachings in Eberhard, which is again the same purpose as the instant invention. Wow!

Given the requirements for and rather irrational decision making required of one of ordinary skill in the art at the time of the instant invention in order for one of ordinary skill in the art to develop the instant invention, Applicant/Owner would like to suggest that the Examiner's citation combination, e.g. Eberhard in view of Wilson and McGrow in view of Reimschuessel and Payne, is "hindsight reconstruction". Applicant/Owner would like to refer the Examiner to MPEP 2144.06 which states:

COMBINING EQUIVALENTS KNOWN FOR THE SAME PURPOSE

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerckhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held *prima facie* obvious). But see *In re Geiger*, 815 F.2d 686, 2 USPQ2d 1276 (Fed. Cir. 1987) ("Based upon the prior art and the fact that each of the three components of the composition used in the claimed method is conventionally employed in the art for treating cooling water systems, the board held that it would have been *prima facie* obvious, within the meaning of 35 U.S.C. 103, to employ these components in combination for their known functions and to optimize the amount of each additive.... Appellant argues... hindsight reconstruction or at best,... 'obvious to try'.... We agree with appellant.").

SUBSTITUTING EQUIVALENTS KNOWN FOR THE SAME PURPOSE

In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact

that the components at issue are functional or mechanical equivalents. *In re Ruff*, 256 F.2d 590, 118 USPQ 340 (CCPA 1958) (The mere fact that components are claimed as members of a Markush group cannot be relied upon to establish the equivalency of these components. However, an applicant's expressed recognition of an art-recognized or obvious equivalent may be used to refute an argument that such equivalency does not exist.); *In re Scott*, 323 F.2d 1016, 139 USPQ 297 (CCPA 1963) (Claims were drawn to a hollow fiberglass shaft for archery and a process for the production thereof where the shaft differed from the prior art in the use of a paper tube as the core of the shaft as compared with the light wood or hardened foamed resin core of the prior art. The Board found the claimed invention would have been obvious, reasoning that the prior art foam core is the functional and mechanical equivalent of the claimed paper core. The court reversed, holding that components which are functionally or mechanically equivalent are not necessarily obvious in view of one another, and in this case, the use of a light wood or hardened foam resin core does not fairly suggest the use of a paper core.); *Smith v. Hayashi*, 209 USPQ 754 (Bd. of Pat. Inter. 1980) (The mere fact that phthalocyanine and selenium function as equivalent photoconductors in the claimed environment was not sufficient to establish that one would have been obvious over the other. However, there was evidence that both phthalocyanine and selenium were known photoconductors in the art of electrophotography. "This, in our view, presents strong evidence of obviousness in substituting one for the other in an electrophotographic environment as a photoconductor." 209 USPQ at 759.).

An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982)."

Applicant/Owner refers the Examiner to MPEP 2141.01 III:

CONTENT OF THE PRIOR ART IS DETERMINED AT THE TIME THE INVENTION WAS MADE TO AVOID HINDSIGHT

The requirement "at the time the invention was made" is to avoid impermissible hindsight. See MPEP § 2145, paragraph X.A. for a discussion of rebutting applicants' arguments that a rejection is based on hindsight.

"It is difficult but necessary that the decisionmaker forget what he or she has been taught . . . about the claimed invention and cast the mind back to the time the invention was made (often as here

many years), to occupy the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art." *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303, 313 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

Applicant/Owner also refers the Examiner to MPEP 2145 X:

ARGUING IMPROPER RATIONALES FOR COMBINING REFERENCES

A. Impermissible Hindsight

Applicants may argue that the examiner's conclusion of obviousness is based on improper hindsight reasoning. However, "[a]ny judgement on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper." *In re McLaughlin* 443 F.2d 1392, 1395, 170 USPQ 209, 212 (CCPA 1971). Applicants may also argue that the combination of two or more references is "hindsight" because "express" motivation to combine the references is lacking. However, there is no requirement that an "express, written motivation to combine must appear in prior art references before a finding of obviousness." See *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1276, 69 USPQ2d 1686, 1690 (Fed. Cir. 2004). For example, motivation to combine prior art references may exist in the nature of the problem to be solved (*Ruiz* at 1276, 69 USPQ2d at 1690) or the knowledge of one of ordinary skill in the art (*National Steel Car v. Canadian Pacific Railway Ltd.*, 357 F.3d 1319, 1338, 69 USPQ2d 1641, 1656 (Fed. Cir. 2004)). See **MPEP § 2143.01** for a discussion of proper motivation to combine references.

McGrow for Claims 1 – 2, 4 – 8, 10 – 13, 15 – 16, 19, 22, 24 – 28, 33 – 38, 40 – 41, 44 – 48, 51 – 55, 58, 67 – 71, 73 – Applicant/Owner would like to respectfully present to the Examiner that, as identified in Applicant/Owner's Declaration, there was no practice of a polymeric quaternary ammonium compound at College Station, TX to dewater biological sludge from a thermophilic digestion process until after teaching of the instant invention by Applicant/Owner.

If McGrow were obvious in the instant invention then why would not McGrow himself or the assignee of McGrow, e.g. Allied Colloids (3rd Party Requestor), have practiced the teachings of McGrow in the instant invention prior to Applicant's Teachings at College Station? As identified in the previous declaration of Richard A. Haase and of Audrey L. Haase, it was only

after the teaching of the instant invention by Applicant/Owner in College Station that Allied Colloids, 3rd Party Requestor, was able to practice the instant invention in College Station. In short, the assignee of McGrow had to copy the instant invention from Applicant/Owner after the teachings of Applicant/Owner in order to realize the instant invention. If the instant invention was non-obvious to the assignee of McGrow, then the instant invention and the instant claims must be non-obvious. Again, as stated previously to the Examiner, McGrow does not teach the dewatering of biological sludge from a thermophilic digestion process. In contrast, McGrow teaches the improvement of dewatering mesophilic bio-solids by reducing coring and underdosing; therein, is the teaching difference. At College Station and at all locations visited by Applicant/Owner, "traditional polyacrylamide polymers used for dewatering [e.g. cationic polyacrylamides alone as identified in McGrow, Dentel and the instant specification] have been shown to perform very poorly in tests for dewatering of sludge from a thermophilic digestion process" (ref. instant specification col. 1 lines 33 – 33).

The above argument is furthered by MPEP 2141.02, which states:

"[A] patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified. This is part of the 'subject matter as a whole' which should always be considered in determining the obviousness of an invention under 35 U.S.C. § 103." *In re Spinnoble*, 405 F.2d 578, 585, 160 USPQ 237, 243 (CCPA 1969). However, "discovery of the cause of a problem ... does not always result in a patentable invention. . . . **[A] different situation exists where the solution is obvious from prior art which contains the same solution for a similar problem.**" *In re Wiseman*, 596 F.2d 1019, 1022, 201 USPQ 658, 661 (CCPA 1979) (emphasis in original)." **(Emphasis added)**

Further, as McGrow does not teach all of the instant claim limitations, e.g. independent claims 1, 22, 33, 41, 48, 55 and 67 in relation to thermophilic or thermophiles, Applicant/Owner would like to cite MPEP 2143.02, which states:

"To establish *prima facie* obviousness of a claimed invention, **all the claim limitations must be taught or suggested by the prior art.** *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). **"All words in a claim must be considered in judging the patentability of that claim against the prior art."** *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an

independent claim is nonobvious under 35 U.S.C. 103, then any claim depending there from is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).” **(Emphasis added)**

In direct support of the facts of copying by others, e.g. assignee of McGrow, as evidenced in the declarations submitted, Applicant/Owner would like to cite MPEP 716.06, which states:

“Evidence of copying was persuasive of nonobviousness when an alleged infringer tried for a substantial length of time to design a product or process similar to the claimed invention, but failed and then copied the claimed invention instead. *Dow Chem. Co. v. American Cyanamid Co.*, 837 F.2d 469, 2 USPQ2d 1350 (Fed. Cir. 1987).” **(Emphasis added)**

To further emphasize the length of time to copy, McGrow was originally filed on October 4, 1990. This is while the previously presented US EPA Document TBS Prakasam, et al. *Effect of Recycling Thermophilic Sludge on the Activated Sludge Process*, EPA Project Summary 5, Sept. 1990 states under the heading of Dewaterability:

“Capillary suction time (CST) measurements at various polymer dosages indicated that mesophilic sludge required a lower polymer dosage than did the thermophilic sludge (10 vs. 22.5 kg/dry tonne) to achieve the minimum CST that was possible. The thermophilic sludge, however, exhibited highest floc strength than did the mesophilic sludge.

Pilot scale centrifuge studies confirmed that the thermophilic sludge required a higher polymer dosage than did the mesophilic sludge. At optimal polymer dosages, those studies also indicated that the mesophilic sludge approached 100% solids capture whereas the thermophilic solids approached a maximum of 96% solids capture. The lower solids capture with thermophilic sludge probably resulted from the higher concentration of fine particles in it than in the mesophilic sludge.”

The report goes on to recommend that:

“Based on the lack of effect on sludge mass and the increase in digestion capability required, the Torpsy process is not recommended for Chicago’s conventional rate activated sludge plants. Nor is thermophilic digestion as the terminal sludge digestion process recommended if the sludge is to be used at a site with nearby neighbors.”

Therefore, as the instant invention was copied by the assignee of McGrow after teaching by Applicant, it is obvious that the teachings of the instant invention were non-obvious to the assignee

of McGrow from the 1990 teachings of McGrow until the teachings of the instant invention by Applicant/Owner in 1996. Further, McGrow published in 1993. At a time wherein McGrow was available to the industry, from 1993 to the time of the instant invention, 1996, if the teachings of McGrow had made the instant invention obvious, then during that time of three years, the instant invention would have been taught and practiced. This is all while the difficulty to dewater biosolids from a thermophilic digestion process was well known as far back as 1990 as evidenced by the US EPA. Therefore, McGrow could not make the instant invention or the instant claims obvious over a time of 6 years. And, if the industry could not make the instant invention and the instant claims obvious over a time of 3 years while having McGrow available, then McGrow must not make the instant invention and the instant claims obvious to the industry. If the instant claims had been obvious in 1996, then College Station would have been operating with the instant invention during the visit of Applicant/Owner or prior to the teachings of Applicant/Owner to College Station.

The same argument is presented for the copying performed in Texarkana, Texas, as evidenced in the presented affidavits and declarations. In the case of Texarkana, Applicant/Owner taught the instant invention and the instant claims to the wastewater operations of Texarkana from 1996 to 1998. This instant invention was copied in Texarkana at the Texarkana Wastewater Facility in 1998. Therefore, in the case of Texarkana, it took the industry 5 years and the assignee of McGrow 8 years to copy the instant invention.

In conclusion, the instant invention is non-obvious by the teachings of McGrow, as is evidenced in the industry and by the assignee of McGrow, 3rd Party Requestor.

Copying and Commercial Success by Others after Teaching of Applicant – Applicant wishes to refer the Examiner to the affidavits and declarations on file which present to the Examiner “copying by others” and “commercial success” by Applicant/Owner, as well as “commercial success” by others after teaching by Applicant/Owner. In combination with this evidence, Applicant/Owner refers the Examiner to MPEP 716.01(a):

OBJECTIVE EVIDENCE MUST BE CONSIDERED WHEN TIMELY PRESENT

Affidavits or declarations, when timely presented, containing evidence of criticality or unexpected results, commercial success, long-felt but unsolved needs, failure of others, skepticism of experts, etc., must be considered by the examiner in determining the issue of obviousness of claims for patentability under 35 U.S.C. 103. The Court of Appeals for the Federal Circuit stated in *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538, 218 USPQ 871,

879 (Fed. Cir. 1983) that "evidence rising out of the so-called 'secondary considerations' must always when present be considered en route to a determination of obviousness." Such evidence might give light to circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or unobviousness, such evidence may have relevancy. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966); *In re Palmer*, 451 F.2d 1100, 172 USPQ 126 (CCPA 1971); *In re Fielder*, 471 F.2d 640, 176 USPQ 300 (CCPA 1973). The *Graham v. John Deere* pronouncements on the relevance of commercial success, etc. to a determination of obviousness were not negated in *Sakraida v. Ag Pro*, 425 U.S. 273, 189 USPQ 449 (1979) or *Anderson's-Black Rock Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 163 USPQ 673 (1969), where reliance was placed upon *A&P Tea Co. v. Supermarket Corp.*, 340 U.S. 147, 87 USPQ 303 (1950). See *Dann v. Johnston*, 425 U.S. 219, 226 n.4, 189 USPQ 257, 261 n. 4 (1976).

Applicant/Owner also refers the Examiner to MPEP 716.01(d):

IN MAKING A FINAL DETERMINATION OF PATENTABILITY, EVIDENCE SUPPORTING PATENTABILITY MUST BE WEIGHED AGAINST EVIDENCE SUPPORTING *PRIMA FACIE* CASE

When an applicant timely submits evidence traversing a rejection, the examiner must reconsider the patentability of the claimed invention. The ultimate determination of patentability must be based on consideration of the entire record, by a preponderance of evidence, with due consideration to the persuasiveness of any arguments and any secondary evidence. *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). The submission of objective evidence of patentability does not mandate a conclusion of patentability in and of itself. *In re Chupp*, 816 F.2d 643, 2 USPQ2d 1437 (Fed. Cir. 1987). Facts established by rebuttal evidence must be evaluated along with the facts on which the conclusion of a *prima facie* case was reached, not against the conclusion itself. *In re Eli Lilly*, 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990). In other words, each piece of rebuttal evidence should not be evaluated for its ability to knockdown the *prima facie* case. All of the competent rebuttal evidence taken as a whole should be weighed against the evidence supporting the *prima facie* case. *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984). Although the record may establish evidence of secondary considerations which are indicia of nonobviousness, the record may also establish such a strong case of obviousness that the objective evidence of nonobviousness is not sufficient to outweigh the evidence of obviousness. *Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 769, 9 USPQ2d 1417, 1427 (Fed.

Cir. 1988), *cert. denied*, 493 U.S. 814 (1989); *Richardson-Vicks, Inc., v. The Upjohn Co.*, 122 F.3d 1476, 1484, 44 USPQ2d 1181, 1187 (Fed. Cir. 1997) (showing of unexpected results and commercial success of claimed ibuprofen and pseudoephedrine combination in single tablet form, while supported by substantial evidence, held not to overcome strong *prima facie* case of obviousness). See *In re Piasecki*, 745 F.2d 1468, 223 USPQ 785 (Fed. Cir. 1984) for a detailed discussion of the proper roles of the examiner's *prima facie* case and applicant's rebuttal evidence in the final determination of obviousness.

If, after evaluating the evidence, the examiner is still not convinced that the claimed invention is patentable, the next Office action should include a statement to that effect and identify the reason(s) (e.g., evidence of commercial success not convincing, the commercial success not related to the technology, etc.). See *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 7 USPQ2d 1222 (Fed. Cir.), *cert. denied*, 488 U.S. 956 (1988). See also MPEP § 716.01. See MPEP § 2144.08, paragraph II.B., for guidance in determining whether rebuttal evidence is sufficient to overcome a *prima facie* case of obviousness.

Applicant/Owner also refers the Examiner to MPEP 716.06:

Another form of secondary evidence which may be presented by applicants during prosecution of an application, but which is more often presented during litigation, is evidence that competitors in the marketplace are copying the invention instead of using the prior art. However, more than the mere fact of copying is necessary to make that action significant because copying may be attributable to other factors such as a lack of concern for patent property or contempt for the patentees ability to enforce the patent. *Cable Electric Products, Inc. v. Genmark, Inc.*, 770 F.2d 1015, 226 USPQ 881 (Fed. Cir. 1985). Evidence of copying was persuasive of nonobviousness when an alleged infringer tried for a substantial length of time to design a product or process similar to the claimed invention, but failed and then copied the claimed invention instead. *Dow Chem. Co. v. American Cyanamid Co.*, 837 F.2d 469, 2 USPQ2d 1350 (Fed. Cir. 1987). Alleged copying is not persuasive of nonobviousness when the copy is not identical to the claimed product, and the other manufacturer had not expended great effort to develop its own solution. *Pentec, Inc. v. Graphic Controls Corp.*, 776 F.2d 309, 227 USPQ 766 (Fed. Cir. 1985). See also *Vandenberg v. Dairy Equipment Co.*, 740 F.2d 1560, 1568, 224 USPQ 195, 199 (Fed. Cir. 1984) (evidence of copying not found persuasive of nonobviousness) and *Panduit Corp. v. Dennison Manufacturing Co.*, 774 F.2d 1082, 1098-99, 227 USPQ 337, 348, 349 (Fed. Cir. 1985), *vacated on other grounds*, 475 U.S. 809, 229 USPQ 478

(1986), *on remand*, 810 F.2d 1561, 1 USPQ2d 1593 (Fed. Cir. 1987) (evidence of copying found persuasive of nonobviousness where admitted infringer failed to satisfactorily produce a solution after 10 years of effort and expense).

Applicant/Owner also refers the Examiner to MPEP 2141:

35 U.S.C. 103 Conditions for patentability; non-obvious subject matter.

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in **section 102** of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

(b)

(1) Notwithstanding subsection (a), and upon timely election by the applicant for patent to proceed under this subsection, a biotechnological process using or resulting in a composition of matter that is novel under **section 102** and nonobvious under subsection (a) of this section shall be considered nonobvious if-

(A) claims to the process and the composition of matter are contained in either the same application for patent or in separate applications having the same effective filing date; and

(B) the composition of matter, and the process at the time it was invented, were owned by the same person or subject to an obligation of assignment to the same person.

(2) A patent issued on a process under paragraph (1)-

(A) shall also contain the claims to the composition of matter used in or made by that process, or

(B) shall, if such composition of matter is claimed in another patent, be set to expire on the same date as such other patent, notwithstanding **section 154**.

(3) For purposes of paragraph (1), the term "biotechnological process" means-

(A) a process of genetically altering or otherwise inducing a single- or multi-celled organism to-

- (i) express an exogenous nucleotide sequence,
- (ii) inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence, or
- (iii) express a specific physiological characteristic not naturally associated with said organism;

(B) cell fusion procedures yielding a cell line that expresses a specific protein, such as a monoclonal antibody; and

(C) a method of using a product produced by a process defined by subparagraph (A) or (B), or a combination of subparagraphs (A) and (B).

(c)

(1) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of **section 102** of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.

(2) For purposes of this subsection, subject matter developed by another person and a claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person if -

(A) the claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made;

(B) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and

(C) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.

(3) For purposes of paragraph (2), the term "joint research agreement" means a written contract, grant, or cooperative agreement entered into by two or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention.<

I. STANDARD OF PATENTABILITY TO BE APPLIED IN OBVIOUSNESS REJECTIONS

Patent examiners carry the responsibility of making sure that the standard of patentability enunciated by the Supreme Court and by the Congress is applied in each and every case. The Supreme Court in *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966), stated:

Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy. . .

This is not to say, however, that there will not be difficulties in applying the nonobviousness test. What is obvious is not a question upon which there is likely to be uniformity of thought in every given factual context. The difficulties, however, are comparable to those encountered daily by the courts in such frames of reference as negligence and scienter, and should be amenable to a case-by-case development. We believe that strict observance of the requirements laid down here will result in that uniformity and definitiveness which Congress called for in the 1952 Act.

Office policy is to follow *Graham v. John Deere Co.* in the consideration and determination of obviousness under 35 U.S.C. 103. As quoted above, the four factual inquiries enunciated therein as a background for determining obviousness are as follows:

- (A) Determining the scope and contents of the prior art;
- (B) Ascertaining the differences between the prior art and the claims in issue;
- (C) Resolving the level of ordinary skill in the pertinent art; and

(D) Evaluating evidence of secondary considerations.

The Supreme Court reaffirmed and relied upon the *Graham* three pronged test in its consideration and determination of obviousness in the fact situations presented in *Sakurada v. Ag Pro, Inc.*, 425 U.S. 273, 189 USPQ 449, *reh'g denied*, 426 U.S. 955 (1976) and *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 163 USPQ 673 (1969). In each case, the Court discussed whether the claimed combinations produced a "new or different function" and a "synergistic result," but it clearly decided whether the claimed inventions were nonobviousness on the basis of the three-way test in *Graham*. Nowhere in its decisions in these cases does the Court state that the "new or different function" and "synergistic result" tests supersede a finding of nonobvious or obviousness under the *Graham* test.

Accordingly, examiners should apply the test for patentability under 35 U.S.C. 103 set forth in *Graham*. See below for a detailed discussion of each of the *Graham* factual inquiries. It should be noted that the Supreme Court's application of the *Graham* test to the fact circumstances in *Ag Pro* was somewhat stringent, as it was in *Black Rock*. Note *Republic Industries, Inc. v. Schlage Lock Co.*, 592 F.2d 963, 200 USPQ 769 (7th Cir. 1979). The Court of Appeals for the Federal Circuit stated in *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1540, 218 USPQ 871, 880 (Fed. Cir. 1983) that

A requirement for "synergism" or a "synergistic effect" is nowhere found in the statute, 35 U.S.C. When present, for example in a chemical case, synergism may point toward nonobviousness, but its absence has no place in evaluating the evidence on obviousness. The more objective findings suggested in *Graham*, *supra*, are drawn from the language of the statute and are fully adequate guides for evaluating the evidence relating to compliance with 35 U.S.C. § 103. *Bowser Inc. v. United States*, 388 F. 2d 346, 156 USPQ 406 (Ct. Cl. 1967).

II. BASIC CONSIDERATIONS WHICH APPLY TO OBVIOUSNESS REJECTIONS

When applying 35 U.S.C. 103, the following tenets of patent law must be adhered to:

- (A) The claimed invention must be considered as a whole;
- (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;

(C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and

(D) Reasonable expectation of success is the standard with which obviousness is determined.

Hodosh v. Block Drug Co., Inc., 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986).

III. OBJECTIVE EVIDENCE MUST BE CONSIDERED

Objective evidence or secondary considerations such as unexpected results, commercial success, long-felt need, failure of others, copying by others, licensing, and skepticism of experts are relevant to the issue of obviousness and must be considered in every case in which they are present. When evidence of any of these secondary considerations is submitted, the examiner must evaluate the evidence. The weight to be accorded to the evidence depends on the individual factual circumstances of each case. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987). The ultimate determination on patentability is made on the entire record. *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). >However, evidence developed after the patent grant in response to challenge to the patent validity's should not be excluded from consideration since "understanding the full range of the invention is not always achieved at the time of filing the patent application." *Knoll Pharms. Co., Inc. v. Teva Pharms. USA Inc.*, 367 F.3d 1381, 1385, 70 USPQ2d 1957, 1960 (Fed. Cir. 2004). (reversing the lower court's grant of summary judgement of invalidity for failure to consider 'unexpected results' evidence obtained from post-filing that could be relevant to the patent validity inquiry).<

See MPEP § 716 - § 716.06 for a discussion of objective evidence and its role in the final legal determination of whether a claimed invention would have been obvious under 35 U.S.C. 103.

Dependant Claims - In addition to the above arguments, Applicant/Owner would like to respectfully quote MPEP Section 2143.03 which states, "If an independent claim is non-obvious under 35 U.S.C. 103, then any claim depending there from is non-obvious *In re Fine*, 837 F2d.1071, 5 USPQ 2d 1596, Fed. Cir. 1988."

Applicant/Owner herein respectfully requests an allowance of claims 1 – 8, 10 – 16, 22, 24 – 28, 33, 35 – 38, 40, 41, 44 – 48, 51 – 55, 58, 67 – 70 and 73 as presented herein; as, the Examiner's argument has been traversed in relation to the independent claims, Applicant/Owner

requests an allowance of all dependent claims there from. Specifically, the Examiner's argument has been traversed relating to independent claim: 1 from which dependant claims 2 – 8 and 10 – 16 have priority; independent claim 22 from which dependent claims 24 – 38 have priority; independent claim 33 from which dependent claims 35 – 38, 40 and 73 have priority; independent claim 41 from which dependent claims 44 – 47 have priority; independent claim 48 from which dependent claims 51 – 54 have priority; independent claim 55 from which dependent claim 58 has priority; independent claim 67 from which dependent claims 68 – 70 have priority.

Recent US Supreme Court Case Law

KSR International v. Teleflex, Inc. et al., No. 04-1350, 550 U.S. __ (2007). Excerpts from this case which support non-obviousness of the instant invention are:

1. In relation to Hindsight Reconstruction:

4. The Federal Circuit's perspective on the problem of hindsight is itself problematic. This Court cautioned in *Graham* against "read[ing] into the prior art the teachings of the invention in issue." 383 U.S. at 36. The Court did not per-

ceive, however, any need for extraordinary showings of obviousness to avoid that danger. The Federal Circuit's rigid test underestimates the capacity of courts and the PTO to avoid the influence of hindsight. Retrospective analysis is not unique to patent law, but regularly arises in a wide variety of contexts, including the determination of the competency of counsel in criminal proceedings, see, e.g., *Rompilla v. Beard*, 125 S. Ct. 2456, 2462 (2005), reasonable use of force by police officers, see, e.g., *Graham v. Connor*, 490 U.S. 386, 396 (1989),

and probable cause, see, e.g., *Maryland v. Garrison*, 480 U.S. 79, 85 (1987). In those situations, as in *Graham*, the Court has consistently recognized that decisionmakers can avoid the improper influence of hindsight by maintaining conscious awareness of its potentially distorting influence in the decisionmaking process.¹⁰ Courts routinely find, for example, an absence of probable cause in cases in which the police in fact find substantial quantities of contraband in a search. There is no reason to think that courts in patent cases cannot be similarly discerning.

2. In relation to innovation beyond the level beyond ordinary skill in the art wherein prior teachings "would have deterred any investigation into the inventor's combination":

Finally, in the only post-*Graham* decision in which the Court has specifically ruled that a claimed invention is nonobvious, *United States v. Adams*, 383 U.S. 39 (1966), the Court did so without suggesting that the mere absence of any teaching, suggestion, or motivation from the prior art would be sufficient to overcome obviousness objections. See *id.* at 51-52. The Court ruled that the invention at issue—a water-activated, constant-voltage battery—was nonobvious, even though it combined elements that were "well known in the prior art" (*id.* at 51), because it demonstrated innovation beyond the level of ordinary skill in the art. The Court explained that the battery performed in a way that was "unexpected" and "far surpassed then-existing wet batteries" (*ibid.*); the teachings of the prior art would have "deter[red] any investigation" into the inventor's combination (*id.* at 52); and "noted experts expressed disbelief in it" (*ibid.*).

3. In relation to commercial success and prior failure of others.

35 U.S.C. 103(a). "The nonobviousness requirement extends the field of unpatentable material beyond that which is known to the public under § 102, to include that which could readily be deduced from publicly available material by a person of ordinary skill in the pertinent field of endeavor." *Bonito Boats*, 489 U.S. at 150 (citing *Graham*, 383 U.S. at 15).

The question of nonobviousness is ultimately one of law, but it turns on "several basic factual inquiries." *Graham*, 383 U.S. at 17. This Court has identified several such inquiries: (1) "the scope and content of the prior art"; (2) "differences between the prior art and the claims at issue"; and (3) "the level of ordinary skill in the pertinent art." *Ibid.* In addition, the Court has stated that "secondary considerations," such as "commercial success" or "long felt but unsolved needs," might provide "indicia of obviousness or nonobviousness." *Id.* at 17-18.

The “ultimate question” of patent validity under Section 103(a) is a question of law. *Graham*, 383 U.S. at 17. It rests on a legal judgment, informed by relevant facts, of whether the hypothetical person having ordinary skill in the art would have found the invention as a whole “obvious.” Section 103(a) itself identifies three “central factors relevant to any inquiry into obviousness” (*Johnston*, 425 U.S. at 226): the scope and content of the prior art, the differences between the prior art and the claims at issue, and the level of ordinary skill in the pertinent art. See *Graham*, 383 U.S. at 17. Other “secondary considerations” —including a long-felt and unfulfilled need for the invention, the prior failures of others, and the commercial success of the invention—may also provide “indicia” supporting the legal conclusion of “obviousness or nonobviousness,” *id.* at 17-18, 35-36, but those considerations will not render an obvious invention patentable. *Anderson’s-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 61 (1969) (citing *Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp.*, 340 U.S. 147, 153 (1950)).

Conclusion

Applicant/Owner has presented technical and legal argument to traverse the Examiner's rejections. Applicant/Owner also referenced previously provided secondary considerations, while providing new secondary considerations in support of non-obviousness of the instant claims. Applicant/Owner has referenced traversal to the most recent US Supreme Court case law.

Applicant/Owner has respectfully traversed all of the Examiner's Rejections while complying with all of the Examiner's Objections. Therefore, Applicant/Owner respectfully requests allowance of all claims as presented herein. Amendments to the claims do not raise any new matter issues; therefore, no additional searching is required.

Applicant/Owner requests that in view of the above facts, the amendment be entered, and after due consideration of the facts presented herein, the claims be allowed and a certificate be issued.

To facilitate the resolution of any issues or questions presented by this paper, Applicant/Owner respectfully requests that the Examiner directly contact the undersigned by phone to further discussion, reconsideration and allowance of the claims.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Richard A. Haase', written over a horizontal line.

Richard A. Haase, Pro Se' Applicant

Date: January 09, 2008

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